

Post Approval Monitoring (PAM)

What is PAM and why do we have it at Virginia Tech?

PAM is the examination of the facilities, procedures, and study documents related to an approved protocol. This assures the university that research subjects are protected and that the PI is in compliance with applicable regulations. PAM verifies that appropriate applications of a study are executed as approved and unanticipated problems/adverse events are reported.

Who is subject to PAM?

All university faculty, staff, visiting scientists, contractors, collaborators, and students who work with biohazardous agents, animals, and/or human subjects.

What can I expect if I am selected?

You will be contacted via email to schedule an appointment for a PAM visit. Reasonable attempts will be made to find a mutually convenient time. Quality detailed records are strongly encouraged in order to facilitate and accelerate the process. Soon thereafter, you will receive a PAM Report in which an assessment of the visit is conveyed and you will be notified if further action is required.

How can I learn more about PAM?

Visit the PAM website link provided on the main Research Compliance website, www.researchcompliance.vt.edu.

Contact Information for the Office of Research Compliance

<http://www.researchcompliance.vt.edu>

IACUC Administrator
540-231-2166
Email: iacucadmin@vt.edu

IBC Administrator
540-231-1910
Email: ibc@vt.edu

IRB Administrator
540-231-4358
Email: irb@vt.edu

IACUC PAM
540-231-7678
Email: iacucpam@vt.edu

IRB PAM Specialist
540-231-0014
Email: irb_pam@vt.edu

For help getting started, please see:
"The Starting Point" at
<http://www.researchcompliance.vt.edu/starting-point>

Mailing Address:
Office of Research Compliance
North End Center
300 Turner Street, Suite 4120 (0497)
Blacksburg, VA 24061
Fax: 540-231-0959

Research Compliance Involving Animals, Biohazardous Agents and/or Human Subjects

What do I Need to Know to Get Started?

If you will be using animal subjects, biohazardous agents or human subjects in research, you must obtain approval from the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC) or Institutional Review Board (IRB) for the planned research activity before any animal acquisitions or human subjects contacts may be made, research may begin, or funding may be released.

Further, Principal Investigators (PIs) are strongly encouraged to keep quality, detailed records throughout their research projects so that documents and data are readily accessible for review during a Post Approval Monitoring (PAM) visit.

The IACUC, IBC, and IRB

Why are the IACUC, IBC, and IRB important?

IACUC/IBC/IRB: Compliance and cooperation with the applicable oversight body (IACUC, IBC or IRB) for your research is required. This ensures the protection of our research subjects and personnel. Failure to comply with applicable federal laws, regulations, and Virginia Tech policies can result in the permanent loss of your research privileges at Virginia Tech. Serious offenses can also result in the loss of all federal funding for all researchers at Virginia Tech.

What activities require IACUC, IBC, or IRB approval?

IACUC: Because the University receives Public Health Service (PHS) funding, **ALL vertebrate animal** activities, except CVM studies using client-owned animals, are to be reviewed by the IACUC, *regardless of funding source*.

IBC: IBC approval is required for all work with infectious agents, human and/or non-human primate agents (even if purchased from a vendor), all modified organisms/plants and/or the use of recombinant/synthetic nucleic acids. This applies *regardless of funding source*.

IRB: IRB approval is required for human subjects research activities designed to develop or contribute to generalizable knowledge (e.g., publication, presentation) for which Virginia Tech is engaged. This includes student dissertation and thesis projects. This applies *regardless of funding source*.

When may I begin my research?

IACUC/IBC/IRB: You may begin work on your study upon receipt of the IACUC, IBC, or IRB Approval Letter for your submission. *Any work begun beforehand violates federal law and puts all research and data obtained in jeopardy.*

Where do I find submission forms and instructions?

IACUC/IBC/IRB: Submission forms and instructions are available at our websites (see below).

What training is required for investigators submitting protocols?

IACUC/IBC/IRB: Training is required before a protocol may be submitted. Training information is provided on our websites:

IACUC: www.researchcompliance.vt.edu/iacuc/

IBC: <https://ibc.researchcompliance.vt.edu/>

IRB: www.irb.vt.edu

How long does it take to process a new submission?

IACUC: IACUC application approval time varies depending on the complexity of the protocol, the involvement of other committees and departments, and the responsiveness of the PI. Please afford ample time for final approval.

IBC: IBC application approval time varies depending on the complexity of the protocol, the involvement of other committees and departments, and the responsiveness of the PI. The IBC meets on the second Tuesday of each month. Protocols must be submitted at least 3 weeks prior to the meeting date.

IRB: Most IRB applications can be reviewed by the IRB office (and not by the actual Board), and typically take 10-14 days for processing and approval. Projects requiring review at a convened meeting by the full Board may take several months for approval.

What do I need to know if I am receiving funds for animal or human subjects research?

IACUC: *Funding cannot be released by the Office of Sponsored Programs (OSP) without an IACUC Approval Letter.* Funding information is to be completed in your IACUC submission. Changes in funding for a protocol are to be updated by the PI via an approved amendment.

IRB: *Funding cannot be released by OSP without an IRB Approval Letter.* Funding information is to be completed in the appropriate section in your IRB submission. Changes in funding are to be reported by the PI to the IRB via email.

What do I need to know about Virginia Tech's Federal Assurances?

IACUC: Virginia Tech is a PHS Assured Institution and is a registered research facility with the USDA:

- Assurance Number - A-3208-01
- Registration Number - 52-R-0012

IRB: Virginia Tech is an Office for Human Research Protections (OHRP) Assured and Registered Institution:

- Assurance Number - FWA00000572
- Registration Number - IRB00000667